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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|-----------------------|---------------------|------------------|
| 10/070,039   | 10/22/2002  | Cristina Alonso-Alija | Le A 33 893         | 9715             |
| 27941  | 7590        | 01/11/2005            | EXAMINER            |                  |
| JEFFREY M. GREENMAN<br>VICE PRESIDENT, PATENTS AND LICENSING<br>BAYER CORPORATION<br>400 MORGAN LANE<br>WEST HAVEN, CT 06516 |             |                       | REYES, HECTOR M     |                  |
|  |             |                       | ART UNIT            | PAPER NUMBER     |
|  |             |                       | 1625                |                  |
| DATE MAILED: 01/11/2005  |             |                       |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/070,039             | ALONSO-ALIJA ET AL. |  |

|                 |                 |  |
|-----------------|-----------------|--|
| <b>Examiner</b> | <b>Art Unit</b> |  |
| Hector M Reyes  | 1625            |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 10 November 2004.  
 2a) This action is **FINAL**.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-20 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) \_\_\_\_\_ is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) 1-20 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

**Lack of Unity/Restriction Election Request**

The instant request vacates previous election request dated 10/07/04.

**Restriction is required under 35 U.S.C. 121 and 372.**

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I.     Claims 3-11 in part and claims 12 and 13 in part drawn to  
**HETEROCYCLIC** derivatives embraced by the said claims, method of preparing the same and pharmaceutical compositions comprising the same, classified in multiple classes and multiple subclasses. **This group may be subjected to further restriction. A single disclosed species is hereby requested for search purpose.**
  
- II.    Claims 3-11 in part and claim 12 in part drawn to **NON-HETEROCYCLIC** derivatives embraced by the said claims, method of preparing the same and pharmaceutical compositions comprising the same, WHEREIN THE FOLLOWING VARIABLES ARE DEFINED AS:
  - B is phenyl
  - R is 0 or 1
  - V is absent or represent O (Oxygen)
  - Q is absent or represent a non-substituted straight chain or branched alkylene

- Y is phenyl optionally substituted with mono to trisubstituted with a straight chain or branched cycloalkyl having 3-8 carbon atoms
- R3 is hydrogen, halogen, non-substituted straight-chain or branched alkyl
- W is a non-substituted straight-chain or branched alkenediyl having in each case up to 6 carbon atoms
- U is a non-substituted straight-chain or branched alkylene having up to 4 carbon atoms
- A is absent or represent a phenyl group
- R2 is COOR<sup>26</sup>, wherein R<sup>26</sup> is hydrogen or straight-chain or branched alkyl having up to 8 carbon atoms or a cycloalkyl having 3-8 carbon atoms
- X represent a non-substituted straight-chain or branched chain alkylene or non-substituted straight-chain or branched alkenediyl having in each case up to 12 carbon atoms
- R1 is COOR<sup>35</sup> wherein R<sup>35</sup> is hydrogen or a non-substituted straight chain or branched alkyl having up to 8 carbon atoms or cycloalkyl having 3-8 carbon atoms,

Compounds embraced by this group are classified in multiple classes and multiple subclasses. **This group may be subjected to further restriction. A single disclosed species is hereby requested for search purpose.**

III. Claims 3-11 in part and claim 12 in part drawn to **NON-HETEROCYCLIC** derivatives embraced by the said claims, method of preparing the said

derivatives and pharmaceutical compositions comprising such derivatives and not embraced by Group II or any other additional group described herein classified in multiple classes and multiple subclasses. **This group may be subjected to further restriction. A single disclosed species is hereby requested for search purpose.**

IV. Claim 1 and 19 drawn to a method of treating **ANY** cardiovascular disorder as described in the said claim, classified in multiple classes and subclasses. **This group may be subjected to further restriction. A single disclosed species is hereby requested for search purpose.**

V. Claims 2 and 20, drawn to a method of treating **arteriosclerosis, hypertension, thromboembolic and venous and fibrotic disorders**, as described in the said claims, classified in multiple classes and subclasses. **This group may be subjected to further restriction. A single disclosed species is hereby requested for search purpose.**

VI. Claims 14, 15, 16, 17 and 18, drawn to multiple methods of using the multiple derivatives embraced by claims 3-11, classified in multiple classes and subclasses. **This group may be subjected to further restriction. A single disclosed species is hereby requested for search purpose.**

The inventions listed as Groups 1-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups III, II and I all are drawn to a particular set of compounds having significantly different structure and reactivity. None of the said Groups posses the same substantial common core, nor is the common existing core novel or seen to be essential to the utility by itself such that the resultant compounds upon substitution of the variables are so structurally diverse that a reference anticipating one Group would not necessarily render the other obvious. Therefore, to search all the different structurally diverse compounds in a single application would present a serious burden on the Office. Moreover, notice that methods described in Groups V and IV do not require the compounds described or embraced by any of the Groups I-III. On the other hand, diseases or disorders treated by the methods described in Group VI while are described as requiring compounds described in claims 3-11, can also be treated by alternative methods very well known in the art, wherein the said compounds are not required. In general terms, all groups described herein are drawn to distinct invention not having an special technical feature and the examination of the whole subject matter described in the claims represent a tremendous burden to the Office.

If Applicant's traverse on the grounds that the inventions are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the groups to be obvious variants or clearly admit on the record that this is the case. In any instance, if the Examiner finds one of the inventions unpatentable over the prior art, the

evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

If Applicant election is drawn to a Group embracing compounds, the Examiner is willing to rejoin one method of using the said elected compounds in the treatment of an specific disease, limited to the scope of allowability of the said compounds and provided that the claims to be rejoin are set free from any 112 issues.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

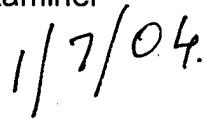
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hector M Reyes whose telephone number is (571) 272-0691. The examiner can normally be reached on M-F (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Ms. Cecilia Tsang can be reach at 571-272 0562 or Examiner primary, Ms. Rita Desai at (571)272-0684. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hector M. Reyes Rivera, PhD Esq.  
US PTO reg. # P-54846  
AU 1625  
January 6, 2005

  
Ms. Rita Desai  
Primary Examiner

  
1/7/04